



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/747,813

12/29/2003

William Dubrul

GMI 1001-4

1880

22470

7590

08/14/2006

HAYNES BEFFEL & WOLFELD LLP

P O BOX 366

HALF MOON BAY, CA 94019

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/747,813

Applicant(s)

DUBRUL ET AL.

Examiner

Lindsey Bachman

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5-28-04, 10-22-04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 1-27-06</u> . |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 28 May 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. This objection is referring to FR 2312264.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because there are handwritten corrections made to some figures. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The

Art Unit: 3734

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16, 38, 46, 63, 67 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose the use of one of the expandable and contractible elements as a sealing device. Furthermore, the specification also fails to disclose the difference between a native and artificial sealing device.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 3734

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-6, 10, 11, 13, 16-27, 31-33, 35, 38-43, 46-52, 56-58, 60, 63-71 and 74 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Samuels (US Patent 5,908,435).

8. Regarding Claim 1, Samuels'435 discloses a device for removing material from the body, such as blood clots in a vessel (column 1, lines 5-12) containing a catheter (21) having a distal end (22) and a proximal end (11) with a lumen (12) extending through, a first expanded and contractible (column 5, lines 7-9) vessel occluding member (62) positioned distal to the distal end (22) of catheter (21), and a second expandable and contractible (column 3, lines 55-57), annular space-blocking element (9) positioned between the first element (62) and the distal end (22) of catheter (21). A membrane sleeve (40) covers second expandable and contractible element (9) (column 4, lines 28-42).

9. Regarding Claim 2, Samuels'435 discloses that the second element (9) is positioned at and extends from the catheter distal end (22) (see Figure 1b).

10. Regarding Claim 3-6, Samuels'435 discloses that the second element (9) contains multiple wing, malecot type elements (9, Figure 1b) and is covered by a membrane (40).

11. Regarding Claim 10, 11, 13, Samuels'435 discloses that the second element (9) contains spaced apart structural members (9, Figure 1b) and a membrane (40) (column 4, lines 28-42).

Art Unit: 3734

12. Regarding Claim 16, Samuels'435 discloses that first element (62) seals the vessel when expanded (see Figure 3e).

13. Regarding Claim 17, Samuels'435 discloses that the second element (9) is funnel-shaped when in its expanded state (see Figure 1b).

14. Regarding Claim 18, Samuels'435 discloses that second element (9) has longitudinally shaped openings (between elements 23).

15. Regarding Claim 19, Samuels'435 discloses that the first element (62) is movable relative to the second element (9) (column 4, line 66 to column 5, line 26).

16. Regarding Claim 20, Samuels'435 discloses that the membrane (40) is impermeable (column 4, lines 28-42).

17. Regarding Claim 21, Samuels'435 discloses that the membrane (40) is elastomeric (column 4, lines 28-42).

18. Regarding Claim 22, Regarding Claim 1, Samuels'435 discloses a device for removing material from the body, such as blood clots in a vessel (column 1, lines 5-12) containing a catheter (21) having a distal end (22) and a proximal end (11) with a lumen (12) extending through, a first expanded and contractible (column 5, lines 7-9) vessel occluding member (62) positioned distal to the distal end (22) of catheter (21), and a second expandable and contractible (column 3, lines 55-57), annular space-blocking element (9) positioned between the first element (62) and the distal end (22) of catheter (21) (see Figure 1b). Further, Samuels'435 discloses that the second element (9) is funnel-shaped when in its expanded state (see Figure 1b) and that second element (9) has longitudinally shaped openings (between elements 23).

Art Unit: 3734

19. Regarding Claim 23, Samuels'435 discloses that the second element (9) is positioned at and extends from the catheter distal end (22) (see Figure 1b).

20. Regarding Claim 24-27, Samuels'435 discloses that the second element (9) contains multiple wing, malecot type elements (9, Figure 1b) and is covered by a membrane (40).

21. Regarding Claim 31-33, and 35, Samuels'435 discloses that the second element (9) contains spaced apart structural members (9, Figure 1b) and a membrane (40) (column 4, lines 28-42).

22. Regarding Claim 38, Samuels'435 discloses that first element (62) seals the vessel when expanded (see Figure 3e).

23. Regarding Claim 39, Samuels'435 discloses that the first element (62) is movable relative to the second element (9) (column 4, line 66 to column 5, line 26).

24. Regarding Claim 40, Samuels'435 discloses that the first element (62) is a balloon (column 5, lines 1-26).

25. Regarding Claim 41, Samuels'435 discloses a device for removing material from the body, such as blood clots in a vessel (column 1, lines 5-12) containing a catheter (21) having a distal end (22) and a proximal end (11) with a lumen (12) extending through, a first expanded and contractible (column 5, lines 7-9) vessel occluding member (62) positioned distal to the distal end (22) of catheter (21), and a second expandable and contractible (column 3, lines 55-57), annular space-blocking element (9) positioned between the first element (62) and the distal end (22) of catheter (21), and a support element (44) extending from the distal catheter end (22). Further,

Art Unit: 3734

Samuels'435 discloses that second element (9) is funnel-shaped when in its expanded state (see Figure 1b) having longitudinally shaped openings (between elements 23) and the second element (9) also contains spaced apart longitudinal members (23).

26. Regarding Claim 42, Samuels'435 discloses that the support element (44) is housed within catheter (21) (see Figure 3a, 3b, or 3c).

27. Regarding Claim 43, Samuels'434 discloses that the support element is slidably housed within the catheter (21) (column 4, line 53 to column 5, line 4).

28. Regarding Claim 46, Samuels'435 discloses that first element (62) seals the vessel when expanded (see Figure 3e).

29. Regarding Claim 47, Samuels'435 discloses a device for removing material from the body, such as blood clots in a vessel (column 1, lines 5-12) containing a catheter (21) having a distal end (22) and a proximal end (11) with a lumen (12) extending through, a first expanded and contractible (column 5, lines 7-9) vessel occluding member (62) positioned distal to the distal end (22) of catheter (21), and a second expandable and contractible (column 3, lines 55-57), annular space-blocking element (9) positioned between the first element (62) and the distal end (22) of catheter (21).

30. Regarding Claim 48, Samuels'435 discloses that the second element (9) is positioned at and extends from the catheter distal end (22) (see Figure 1b).

31. Regarding Claim 49-52, Samuels'435 discloses that the second element (9) contains multiple wing, malecot type elements (23, Figure 1b) and is covered by a membrane (40).

Art Unit: 3734

32. Regarding Claim 56-58, and 60, Samuels'435 discloses that the second element (9) contains spaced apart structural members (23, Figure 1b) and a membrane (40) (column 4, lines 28-42).

33. Regarding Claim 63, Samuels'435 discloses that first element (62) seals the vessel when expanded (see Figure 3e).

34. Regarding Claim 64, Samuels'435 discloses that the second element (9) is funnel-shaped when in its expanded state (see Figure 1b).

35. Regarding Claim 65, Samuels'435 discloses that second element (9) has longitudinally shaped openings (between elements 23).

36. Regarding Claim 66, Samuels'435 discloses that the first element (62) is movable relative to the second element (9) (column 4, line 66 to column 5, line 26).

37. Regarding Claim 67, Samuels'435 discloses that first element (62) seals the vessel when expanded (see Figure 3e).

38. Regarding Claim 68, Samuels'435 discloses that the first element (62) is a balloon (column 5, lines 1-26).

39. Regarding Claim 69, Samuels'435 discloses a device for removing material from the body, such as blood clots in a vessel (column 1, lines 5-12) containing a catheter (21) having a distal end (22) and a proximal end (11) with a lumen (12) extending through, and a second expandable and contractible (column 3, lines 55-57), annular space-blocking element (9) positioned at the distal end (22) of catheter (21). Further, Samuels'435 discloses that the annular space-blocking element (9) is funnel-shaped when in its expanded state (see Figure 1b) for receipt of material (52) (see Figure 3d

Art Unit: 3734

and 3e). Samuels'435 also discloses that the annular space-blocking element (9) contains spaced apart structural members (23, Figure 1b) and a membrane (40) (column 4, lines 28-42).

40. Regarding Claim 70, Samuels'435 discloses that the membrane (40) is impermeable (column 4, lines 28-42).

41. Regarding Claim 71, Samuels'435 discloses that the membrane (40) is elastomeric (column 4, lines 28-42).

42. Regarding Claim 74, Samuels'435 discloses that element (9) seals the vessel when ring (26) is expanded (see Figure 3b and 3e).

Claim Rejections - 35 USC § 103

43. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

44. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 3734

45. Claims 7-9, 12, 14, 15, 28-30, 34, 36, 37, 44, 45, 53-55, 59, 61, 62, 72, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuels'435, as applied to Claims 1, 22, 41, 47, and 69, in further view of Hart, et al. (US Patent 5,868,708).

46. Samuels'435 discloses the limitations of Claim 1, 22, 41, 47, and 69, as described above. Samuels'435 does not teach that the first expandable element comprises a braided element with spaced apart structural members covered or the use of a sheath on the first element. Samuels'435 also does not disclose that both elements are covered with a braided element.

47. Hart'708 teaches the use of a first expandable and collapsible (column 8, lines 61-64) element (56) and a second expandable and collapsible (column 8, lines 61-64) element (62) (Figure 10) in a surgical device for removing obstructing material in a vascular conduit (column 1; lines 11-26). Regarding Claim 7, 28 44, and 53, Hart'708 teaches that the first element (56) is surrounded with a braided element (66, Figure 10) in order to be used for improved removal of occlusive material and traction (column 1, line 60 to column 2, line 15). Regarding Claim 8, 9, 29, 30, 54, and 55, Hart'708 teaches that the first element (56) contains spaced apart structural members (66, Figure 10) and a membrane (balloon, 62) because the membrane (balloon) is used to expand and contract the braided element, in which the spaced apart structural members make the braided element expandable and contractible (column 2, lines 37-51 and column 7, lines 48-54)). Regarding Claims 15, 37, 45, and 62, Hart'708 teaches that the inside surface of the first expandable element comprises a braided element (66) covered with a

Art Unit: 3734

membrane (balloon, 62) in order to expand the first element. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a braided element on the first expandable element because it is useful for removing occluding material from an artery because it provides traction.

48. Regarding Claim 12, 14, 34, 36, 59, and 61, Hart'708 teaches that the first element (56) is surrounded with a braided element (66, Figure 10) and the second element (62) is also surrounded with a braided element (64, Figure 10) in order to create a space between the two elements for capturing emboli debris when the device is in use (column 4, lines 8-22). Both braided elements contain structural members (column 7, lines 25-39) in order to retain the membranes (both labeled as 62 in Figure 10). Therefore it would have been obvious to one skilled in the art at the time the invention was made to require that both expandable and contractible elements contain structural members in order to retain the balloon.

49. Regarding Claim 72, Hart'708 teaches that the expandable and contractible element (56) contains a braided element (66, Figure 10) in order to be used for improved removal of occlusive material and traction (column 1, line 60 to column 2, line 15).

50. Regarding Claims 73, Hart'708 teaches that the inside surface of the expandable element (56) comprises a braided element (66, Figure 10) covered with a membrane (balloon, 62) in order to expand the first element.

Art Unit: 3734

51. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a braided element on the first expandable element because it is useful for removing occluding material from an artery because it provides traction.

Conclusion

52. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lenker, et al. (US Patent 5,683,451).

53. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

54. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

55. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lmb

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER